

**REMARKS**

Claim 1, 7, 12, 15, 24 and 26 have been amended. Claims 6 and 27 have been canceled. Claims 20 - 22 have been withdrawn. No new matter has been added. Thus, claims 1 - 5, 7 - 19 and 23 - 26 remain pending in the present application. It is submitted that, in view of the above amendments and the following remarks, all of the presently pending claims are in condition for allowance.

Claims 15 - 17 and 23 - 26 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,244,379 to Smith ("Smith").

Amended claim 15 recites "[a] *dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line; a valve element mounted within the flow passage of the housing, the valve element including a flexible disk extending across the flow passage, the flexible disk including a plurality of movable elements formed on opposite sides of a first slit extending through the flexible disk, the moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the flexible disk, the moveable elements are maintained in a closed position in which no flow is permitted past the flexible disk and, when a pressure at least as great as the threshold value is applied to the flexible disk, the moveable elements are moved to an open position separated from one another along the first slit permitting flow through the flow passage, the valve element further comprising biasing elements coupled to the flexible disk adjacent to the first slit to urge the moveable elements toward the closed position.*"

Smith fails to teach or suggest a "valve element further comprising biasing elements coupled to the flexible disk adjacent to the first slit to urge the moveable elements toward the

closed position,” as recited in claim 15. Rather, the Smith disclosure does not teach any biasing elements at all. Specifically, the valve member 130 of Smith is not coupled to any element at all, much less to multiple biasing elements coupled adjacent the first slit to urge the moveable elements toward the closed position.

Smith therefore fails to teach or suggest a “valve element further comprising biasing elements coupled to the flexible disk adjacent to the first slit to urge the moveable elements toward the closed position,” as recited in claim 15. It is therefore submitted that claim 15 and its dependent claims 16 - 17 and 23 - 25 are allowable over Smith for at least this reason.

Furthermore, it is respectfully submitted that Smith also fails to teach or suggest a “*dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line*” in combination with “a valve element mounted within the flow passage of the housing,” as recited in claim 15. Rather, Smith is directed only to the withdrawal of blood from the body. (See Smith, col. 4, ll. 7 - 13). Specifically, Smith is directed to a one-way valve apparatus wherein the valve member 130 opens in response to a suction force applied from a direction opposite the backing member 140 to permit fluid withdrawal from the body. (See Smith, col. 5, ll. 34 - 57; Fig. 2). It is noted that the recited limitation of “a valve housing *having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line*” in claim 15 is a structural limitation that restricts a structure of the recited valve element. Specifically, it is well known in the art that dialysis procedures require that fluids be withdrawn from and infused into the body. Thus, it is evident from the recitation of claim 15 that the “valve element” must be structured such that a connection thereof to a patient line and a dialysis line can facilitate dialysis (i.e., permit a two-way fluid flow therepast). The valve member 130 of Smith device is inherently incapable of functioning in dialysis applications as it permits fluid flow in only

one direction, specifically in the direction from the proximal needle 122 to the distal needle 128 to remove a fluid from the body. (*Id.* at col. 5, ll. 34 - 57, Fig. 2). Furthermore, as noted above, Smith is directed only to the withdrawal of blood from the body and explicitly recites the undesirability of injecting any blood into the body. (*Id.* at col. 5, ll. 34 - 39). Smith therefore teaches away from a “*dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line*” in combination with “*a valve element mounted within the flow passage of the housing,*” as recited in claim 15.

Accordingly, it is submitted that Smith also fails to teach or suggest a “*dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line*” in combination with “*a valve element mounted within the flow passage of the housing,*” as recited in claim 15 and that claim 15 is therefore allowable over Smith for this additional reason. Because claims 16 - 17 and 23 - 25 depend from, and therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Amended claim 26 recites limitations substantially similar to claim 15, including “[a] *flow shutoff device for dialysis applications, comprising: a housing attachable to a patient line; and a pressure actuated valve mounted within the housing to selectively restrict flow therethrough, the valve comprising a flexible disk including a plurality of movable elements separated by a slit extending through the disk [...], the pressure actuated valve further comprising at least one biasing member coupled thereto to increase a biasing force urging the movable elements toward the closed position.*” It is therefore submitted that claim 26 is allowable over Smith for the same reasons stated above in regard to claim 15.

Claims 1 - 5, 7, 9 - 17 and 23 - 26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,324,274 to Martin in view of Smith. In support of the rejection, the Examiner stated that it would have been obvious to have employed the pressure actuated valve assembly of Smith in the dual-lumen catheter of Martin. (See 12/8/08 Office Action, pp. 3 - 4).

Amended claim 1 recites a valve apparatus for dialysis applications, comprising “a first flexible disk extending across a first lumen through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk [...] *the first flexible disk further comprising at least one biasing member coupled thereto adjacent the first slit to increase a biasing force urging the first movable elements toward the closed position* and further comprising a second lumen with a second flexible disk extending thereacross[...].”

Martin fails to teach or suggest a “first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk [...] *the first flexible disk further comprising at least one biasing member coupled thereto adjacent the first slit to increase a biasing force urging the first movable elements toward the closed position*,” as recited in claim 1. The Examiner has affirmed this and cited Smith to overcome this deficiency. (See 12/8/08 Office Action, p. 3). However, as noted above, Smith also fails to teach or suggest a “first flexible disk further comprising at least one biasing member coupled thereto adjacent the first slit to increase a biasing force urging the first movable elements toward the closed position,” as recited in claim 1. Rather, Smith does not teach or suggest any biasing element at all. It is therefore respectfully submitted that Martin and Smith, taken either alone or in combination, fail to teach or suggest a “first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk [...] *the first flexible disk further comprising at least one biasing member coupled thereto adjacent the first slit to increase a biasing force urging the first*

*movable elements toward the closed position ,”* as recited in claim 1 and that claim 1 is therefore in condition for allowable. Because claims 2 - 5, 7 and 9 - 14 depend from, and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable

Furthermore, it is respectfully submitted that the modification proposed by the Examiner would be detrimental to the Martin device as it would prevent the intake and return lumens of Martin from functioning properly. Specifically, the Martin device is directed to a dual-lumen catheter with a first lumen connected to one of the tubes 38 or 40 and opening at a distal end of the main body 22 at the openings 54 and a second lumen connected to the other one of the tubes 38 or 40 and opening at a distal end of the main body 22 at the openings 56. (See Martin, col. 2, li. 56 – col. 3, li. 2; Fig. 1). Martin further recites that one lumen “is normally the return lumen and the other lumen is the intake lumen and will originate at openings 54 providing entry to the catheter.” (*Id.* at col. 2, li. 62 - 65). Since the valve member 130 of Smith is a “one-way valve permitting blood flow [...] in one direction only, and [preventing] inadvertent blood flow when the removal of blood is not desired,” modifying the Martin device to include the valve member 130 would be detrimental thereto as the backing disk 140 would prevent the infusion of fluid into the body.” (See Smith, col. 5, li. 34 - 38, li. 48 - 53; Fig. 2).

Furthermore, if the valve of Smith were to be modified with one valve placed in the Martin device in a normal configuration (i.e., allowing only withdrawal of blood) and a second valve placed in a reverse configuration (i.e., allowing only infusion of blood), the modification would still prove to be detrimental as there would be no means of actuating the reverse configuration valve. Specifically, Smith notes that the valve member 130 is actuated by the application of a suction or slight vacuum to an interior cavity to cause the valve member 130 to flex outward and force the slit 132 to open. (See Smith, col. 5, li. 41 - 44). It is noted that there would be no available means to apply a suction to a distal end of the reverse

configuration valve, wherein the distal end would be the direction approaching the body. Specifically, there would be no way to apply a suction or vacuum from inside the body and thus, no available means of opening the reverse configuration valve to flow. Accordingly, an infusion procedure would still not be possible with the valve of Smith.

The Examiner has further indicated that the valve of Smith is designed “with a thickness sized so as to selectively determine the force necessary to force open the slit 32 with fluid pressure.” (See 12/8/08 Office Action, p. 6; See Also Smith, col. 3, ll. 23 - 27). However, it is respectfully submitted that the cited recitation of Smith refers to a first embodiment comprising the valve member 30, which is formed as a closed, elongated sleeve-shaped member and does not meet the limitation of a “first flexible disk extending across a first lumen,” as recited in claim 1. (See Smith, col. 3, ll. 11 - 27; Fig. 1). It is further submitted that the aforementioned recitation of Smith cannot be applied to the second embodiment comprising the valve member 130 since the valve member 30 opens in response to a fluid pressure while the valve member 130 is formed such that it only opens to flow under a predetermined vacuum pressure due to its engagement with the backing member 140. (See Smith, col. 5, ll. 34 - 57; Fig. 2). It is therefore respectfully submitted that the valve member 130 of Smith is incapable of opening under fluid pressure and that the modification proposed by the Examiner would be detrimental to the Martin device as it would prevent the intake lumen from functioning.

It is therefore noted that the proposed modification is not allowable and that Martin and Smith, taken either alone or in combination, fail to teach or suggest “[a] *valve apparatus for dialysis applications*, comprising a first flexible disk extending across a first lumen [...] *and further comprising a second lumen wherein a second flexible disk extends across the second lumen*,” as recited in claim 1 and that claim 1 is therefore allowable for at least this additional reason. Because claims 2 - 5, 7 and 9 - 14 depend from, and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 15 recites limitations substantially similar to claim 1, including a “*dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line*” in combination with “a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line” and “*biasing elements coupled to the flexible disk to urge the movable elements toward the closed position.*” It is therefore respectfully submitted that claim 15 is allowable over Martin and Smith for the same reasons noted above with respect to claim 1. Because claims 16 - 17 and 23 - 25 depend from, and therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claim 26 also recites limitations substantially similar to claim 1, including “[a] flow shutoff device for dialysis applications” with a pressure actuated valve “*comprising at least one biasing member coupled thereto to increase a biasing force urging the movable elements toward the closed position.*” It is therefore submitted that claim 26 is allowable over Martin and Smith for the same reason noted above with regard to claims 1 and 15.

Claims 8 and 18 - 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Martin in view of Smith in further view of Jones.

Claim 8 depends from, and therefore includes all of the limitations of claim 1. As noted above, Martin and Smith fail to teach the limitations of claim 1. It is respectfully submitted that Jones fails to cure the deficiencies noted above in regard to claim 1. Accordingly, it is submitted that claim 1 is allowable over Martin, Smith and Jones, taken either alone or in combination and that claim 8 is allowable for the same reasons stated above in regard to claim 1.

Claims 18 and 19 depend from, and therefore includes all of the limitations of claim 15. As noted above, Martin and Smith fail to teach the limitations of claim 15. Jones fails to cure

this deficiency. Accordingly, it is submitted that claim 15 is allowable over Martin, Smith and Jones, either alone or in combination. It is submitted that claims 18 and 19 are therefore allowable as dependent on an allowable base claim.

Claims 1 - 19 and 23 - 26 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 29 of U.S. Patent No. 7,435, 236. In view of the terminal disclaimer submitted herewith, Applicants submits that this rejection has been obviated.



**CONCLUSION**

All issues raised by the Examiner having been addressed. Applicants therefore submit that the application is in condition for allowance.

Respectfully submitted,

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